

Application Number 10/723,316  
Responsive to Office Action mailed April 7, 2006

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**REMARKS**

This Amendment is responsive to the Office Action dated April 7, 2006. Applicant has amended claims 1, 5, 23, 26 and 27, and added claims 28-32. Claims 1-32 are pending.

**Rejections for Obviousness-type Double Patenting:**

The Examiner provisionally rejected claims 1-27 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 and 36-37 of copending Application No. 10/236,578; claims 1-6 and 10-23 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 and 29-31 of copending Application No. 10/422,077; claims 7-8 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32 and 38 of copending Application No. 10/723,903; claims 7-8 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32 and 38 of copending Application No. 10/745,757; claim 27 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,355; claim 27 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,840; claims 7-8 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/836,924; claims 7-8 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/836,927; claim 27 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,970; and claim 27 under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/837,181.

Applicants note the provisional status of these rejections. Accordingly, Applicants will address this issue if and when the rejection is formally applied.

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**Claim Rejections Under 35 U.S.C. § 102**

*"Neural Stimulation as a Method of Controlling Prostatitis Systems" (Chalfin)*

The Office Action rejected claims 1-2, 9, 14-19, 24 and 26 under 35 U.S.C. § 102(b) as being anticipated by Chalfin. Applicant respectfully traverses this rejection to the extent the rejection is considered applicable to the claims as amended. Chalfin fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, as amended, independent claim 1 recites a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in one of the sacral splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof.

Chalfin fails to disclose or suggest this requirement of independent claim 1. Instead, as recognized in the Office Action, Chalfin describes sacral nerve stimulation for prostatitis. The disclosure of sacral nerve stimulation in Chalfin would not have suggested implantation of a lead in any of the locations recited by amended independent claim 1 to one of ordinary skill in the art.

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As another example, Chalfin fails to disclose or suggest concomitantly delivering a drug to the patient and delivering the electrical stimulation regime, as required by claim 26, as amended. In fact, Chalfin expressly teaches away from this feature. With respect to delivery of drugs, Chalfin states:

Bladder retraining, pelvic floor exercises, biofeedback, and anti-cholinergic drug therapy (oxybutynin, tolterodine) are effective measures to treat this problem.

However, some patients remain resistant to therapy. For this group of patients unilateral sacral nerve stimulation offers a safe and nondestructive alternative.<sup>1</sup>

Accordingly, Chalfin would not have suggested concomitantly delivering a drug to the patient and delivering the electrical stimulation regime, as required by claim 26, to one of ordinary skill in the art.

Chalfin fails to disclose each and every limitation set forth in claims 1-2, 9, 14-19, 24 and 26. For at least this reason, the Office Action has failed to establish a *prima facie* case for anticipation of Applicant's claims 1-2, 9, 14-19, 24 and 26 by Chalfin under 35 U.S.C. § 102(b). Withdrawal of this rejection is respectfully requested.

*US 5,454,840 to Krakovsky et al. (Krakovsky)*

The Office Action also rejected claims 1, 2, 7-8 and 14-27 under 35 U.S.C. § 102(b) as being anticipated by Krakovsky. Applicant respectfully traverses this rejection to the extent the rejection is considered applicable to the claims as amended. Krakovsky fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, like Chalfin, Krakovsky fails to disclose or suggest a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in one of the sacral splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions

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<sup>1</sup> Emphasis added.

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thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 1.

Instead, as recognized in the Office Action, Krakovsky describes stimulation of the pelvic splanchnic nerve or pudendal nerve for treatment of sexual dysfunction. The disclosure of pelvic splanchnic nerve or pudendal nerve stimulation in Krakovsky would not have suggested implantation of a lead in any of the locations recited by amended independent claim 1 to one of ordinary skill in the art.

As another example, Krakovsky fails to disclose or suggest generating and delivering electrical pulses having pulse widths ranging between about 180 microseconds and about 450 microseconds, between about 100 microseconds and about 1000 microseconds, and between about 10 microseconds and about 5000 microseconds, as required by claim 22. Instead, Krakovsky discloses a pulse width of 100,000 microseconds.<sup>2</sup> The disclosure of a pulse width of 100,000 microseconds in Krakovsky would not have suggested any of the pulse width ranges recited in claim 22 to one of ordinary skill in the art.

Krakovsky fails to disclose each and every limitation set forth in claims 1, 2, 7-8 and 14-27. For at least this reason, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 1, 2, 7-8 and 14-27 by Krakovsky under 35 U.S.C. § 102(b). Withdrawal of this rejection is respectfully requested.

*US 6,002,964 Feler et al. (Feler)*

The Office Action also rejected claims 1-4, 7-9, 14-15 and 17-20 under 35 U.S.C. § 102(b) as being anticipated by Feler. Applicant respectfully traverses this rejection to the extent the rejection is considered applicable to the claims as amended. Feler fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, like Chalfin and Krakovsky, Feler fails to disclose or suggest a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in one of the sacral splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the urethra or

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<sup>2</sup> Krakovsky, FIGS. 12 and 13 (disclosing 0.1 second).

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portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 1.

Instead, as recognized in the Office Action, Feler describes stimulation of the sacral nerve roots to treat pelvic pain. The disclosure of sacral nerve root stimulation in Feler would not have suggested implantation of a lead in any of the locations recited by amended independent claim 1 to one of ordinary skill in the art.

Feler fails to disclose each and every limitation set forth in claims 1-4, 7-9, 14-15 and 17-20. For at least this reason, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 1-4, 7-9, 14-15 and 17-20 by Feler under 35 U.S.C. § 102(b). Withdrawal of this rejection is respectfully requested.

*US 6,238,423 to Bardy (Bardy)*

The Office Action rejected claims 1-5 and 10-23 under 35 U.S.C. § 102(b) as being anticipated by Bardy. Applicant respectfully traverses this rejection to the extent the rejection is considered applicable to the claims as amended. Bardy fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Bardy also fails to disclose or suggest a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in one of the sacral splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof,

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greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 1.

Instead, as recognized in the Office Action, Bardy discloses delivering stimulation to the colon to treat gastrointestinal disorders. The disclosure of colon stimulation in Bardy would not have suggested implantation of a lead in any of the locations recited by amended independent claim 1 to one of ordinary skill in the art.

As another example, Bardy fails to disclose or suggest generating and delivering electrical pulses having frequencies ranging between about 50 Hz and about 100 Hz, between about 10 Hz and about 250 Hz, and between about 0.5 Hz and about 500 Hz, as required by claim 20.

Instead, Bardy discloses delivering pulses at no less than 1000 Hz.<sup>3</sup> The disclosure of frequencies no less than 1000 Hz in Bardy would not have suggested any of the frequency ranges recited in claim 20 to one of ordinary skill in the art.

Further, as another example, Bardy fails to disclose or suggest generating electrical pulses having varying spatial or temporal phases for respective delivery to the first and at least a second lead, as required by claim 23, as amended. The pulse trains illustrated by FIGS. 6 and 7 of Bardy are described as alternatives.<sup>4</sup> Bardy does not suggest that the pulse trains are delivered respectively to first and second leads. Accordingly, Bardy would not have suggested generating electrical pulses having varying spatial or temporal phases for respective delivery to the first and at least a second lead, as required by amended claim 23, to one of ordinary skill in the art.

Bardy fails to disclose each and every limitation set forth in claims 1-5 and 10-23. For at least this reason, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 1-5 and 10-23 by Bardy under 35 U.S.C. § 102(b). Withdrawal of this rejection is respectfully requested.

<sup>3</sup> Bardy, col. 12, ll. 22-24 (disclosing a maximum of 1 millisecond between pulses).

<sup>4</sup> Bardy, text accompanying FIGS. 6 and 7.

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*US 6,449,512 to Boveja (Boveja)*

The Office Action also rejected claims 1-2, 11, 14-15, 17-24 under 35 U.S.C. § 102(b) as being anticipated by Boveja. Applicant respectfully traverses this rejection to the extent such rejection may be considered applicable to the amended claims. Boveja fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Boveja also fails to disclose or suggest a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in one of the sacral splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by amended independent claim 1.

Instead, as recognized in the Office Action, Boveja teaches sacral nerve stimulation to treat urinary incontinence. The disclosure of sacral nerve stimulation in Boveja would not have suggested implantation of a lead in any of the locations recited by amended independent claim 1 to one of ordinary skill in the art.

As other examples, Boveja fails to disclose or suggest the voltage pulse amplitude ranges recited by claim 21, or generating electrical pulses having varying spatial or temporal phases for respective delivery to the first and at least a second lead, as required by amended claim 23. Col. 7, ll. 33-67 of Boveja, cited in the Office Action, only discloses current amplitudes, and does not suggest that the described different stimulation states are delivered to respective leads.

Boveja fails to disclose each and every limitation set forth in claims 1-2, 11, 14-15, 17-24. For at least this reason, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 1-2, 11, 14-15, 17-24 by Boveja under 35 U.S.C. § 102(b). Withdrawal of this rejection is respectfully requested.

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**Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 4-8 and 10-13 under 35 U.S.C. § 103(a) as being unpatentable over Chalfin, or Feler, or Boveja in view of US 6,055,456 to Gerber (Gerber). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

As discussed above, Chalfin, Feler, and Boveja fail to disclose or suggest each of every feature of Applicant's independent claim 1, as amended. Gerber does not provide any teaching that would have overcome the basic deficiencies of Chalfin, Feler, and Boveja with respect to the requirements of the independent claim. For at least that reason, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims 4-8 and 10-13 under 35 U.S.C. § 103(a). Withdrawal of this rejection is respectfully requested.

**New Claims:**

Applicant has added claims 28-32 to the pending application. No new matter has been added by the new claims. Furthermore, the applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

For example, the reference fail to disclose or suggest a method for treating urinary voiding dysfunction, urge frequency disorder, or urinary retention disorder comprising implanting a first lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof, the hypogastric nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof,

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Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by new independent claim 28.

As another example, the reference fail to disclose or suggest a method for treating at least one of pelvic pain, prostatitis, prostatalgia or prostatodynia comprising implanting a first lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof, the hypogastric nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by new independent claim 30.

Further, the applied references fail to disclose or suggest a method for treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia in a patient, comprising implanting a first lead in tissue of the patient adjacent, around or in the pudendal nerve or branches or portions thereof, as required by new independent claim 32.

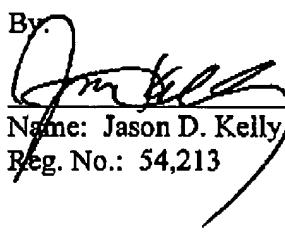
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### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: July 14, 2006

By:



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